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U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

NEW

EXPRESS MAIL LABEL NO.

10/589562

PRIORITY DATE CLAIMED

INTERNATIONAL APPLICATION NO.

PCT/EP2005/050401

INTERNATIONAL FILING DATE

January 31, 2005

February 18, 2004

October 28, 2004

TITLE OF INVENTION

METHOD FOR VERIFYING THE FEASIBILITY OF A MEDICAL STUDY USING ACCEPTANCE CRITERIA FOR PATIENTS

APPLICANT(S) FOR DO/EO/US

Klaus ABRAHAM-FUCHS, Rainer KUTH, Dr. Eva RUMPEL, Markus SCHMIDT, Dr. Siegfried SCHNEIDER, Horst SCHREINER, and Dr. Gudrun ZAHLMANN

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is transmitted herewith.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4)
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☒ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 20. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98-1449, International Search Report (PCT/ISA/210 and PCT/ISA/220) in English and PTO Form 1449
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☒ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Formal Drawing; Article 34 Amended Sheet; PCT/IPEA/416; PCT/ISA/237; PCT/IPEA/409

U.S. APPLICATION NO (if known, see 37 CFR 1.5) <div style="font-size: 24pt; font-weight: bold;">10/589562</div>		INTERNATIONAL APPLICATION NO PCT/EP2005/050401		ATTORNEY'S DOCKET NUMBER 32860-001072/US	
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21. <input checked="" type="checkbox"/> The following fees are submitted: PCT FEES – NATIONAL STAGE: <table style="width:100%;"> <tr> <th style="text-align: left;">Fee Code</th> <th style="text-align: left;">Description</th> <th style="text-align: left;">Fee</th> </tr> <tr> <td>1631</td> <td>Basic National Stage Fee.....</td> <td>\$300.00</td> </tr> <tr> <td>1632</td> <td>National Stage Search Fee.....</td> <td>\$400.00</td> </tr> <tr> <td>1633</td> <td>National Stage Examination Fee.....</td> <td>\$200.00</td> </tr> </table> ENTER APPROPRIATE FEE AMOUNT =				Fee Code	Description	Fee	1631	Basic National Stage Fee.....	\$300.00	1632	National Stage Search Fee.....	\$400.00	1633	National Stage Examination Fee.....	\$200.00	CALCULATIONS PTO USE ONLY <div style="border: 1px solid black; padding: 5px;"> \$ <u>900.00</u> </div>	
Fee Code	Description	Fee															
1631	Basic National Stage Fee.....	\$300.00															
1632	National Stage Search Fee.....	\$400.00															
1633	National Stage Examination Fee.....	\$200.00															
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 Months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ _____													
PAGES	PAGES FILED	EXTRA PAGES FILED IN 50 PAGE SEGMENTS	RATE														
Total Pages	15 - 100 = 0	0	X 250.00	\$ <u>0.00</u>													
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE														
Total Claims	12 - 20 =	0	X 50.00	\$ <u>0.00</u>													
Independent Claims	1 - 3 =	0	X 200.00	\$ <u>0.00</u>													
MULTIPLE DEPENDENT CLAIM(S) (if applicable) _____			+ 360.00	\$ <u>0.00</u>													
TOTAL OF ABOVE CALCULATIONS =				\$ <u>900.00</u>													
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ _____													
SUBTOTAL =				\$ <u>900.00</u>													
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 Months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ _____													
TOTAL NATIONAL FEE =				\$ <u>900.00</u>													
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$ <u>40.00</u>													
TOTAL FEES ENCLOSED =				\$ <u>940.00</u>													
				Amount to be:	\$												
				refunded													
				charged	\$												

a. ☒ A check in the amount of **\$940.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account. No. 08-0750 in the amount of \$ _____ to cover the above fees.
 A triplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 08-0750.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:
Harness, Dickey & Pierce, P.L.C – Customer No. 30596
Post Office Box 8910
Reston, Virginia 20195

Date: August 16, 2006

By Donald J. Daley
 Donald J. Daley, #34,313

DJD:dpg

10/589562

IAP11 Rec'd PCT/PTO 16 AUG 2006

PATENT

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant(s): Klaus ABRAHAM-FUCHS et al.
Int'l Application No.: PCT/EP2005/050401
Application No.: NEW APPLICATION
Filed: August 16, 2006
For: METHOD FOR VERIFYING THE FEASIBILITY OF A
MEDICAL STUDY USING ACCEPTANCE CRITERIA FOR
PATIENTS

LETTER

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314
Mail Stop PCT

August 16, 2006

Sir:

Amended claims are attached hereto (which correspond to Article 34 amendments or to claims attached to the International Preliminary Examination Report), as required by 35 U.S.C. § 371(c)(3). The Article 34 amended claims are incorporated in the included substitute specification and Preliminary Amendment.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

By: 
Donald J. Daley, Reg. No. 34,313

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New Patent Claim 1

1. A method for verifying the feasibility of a medical project with acceptance criteria (4) for patients, having the following steps:

- target criteria (6) are set for the project,
- a patient group (17) comprising potential patients is selected with the aid of the acceptance criteria (4) from a database (10) containing patient data (14) of patients,
- the patient data (14) of the patient group (17) are evaluated with the aid of the target criteria (6) and a measure (21) of the feasibility of the project is calculated.